REMARKS

I. APPLICANTS' INVENTION

The present invention relates to an endoprosthesis assembly including an implantable prosthesis (e.g., a diametrically expandable stent device, with or without a graft covering) provided with a delicate constraining sheath located coaxially around the endoprosthesis. The assembly is further provided with means for disruption of the constraining sheath (e.g., a catheter balloon) to initiate deployment of the endoprosthesis. The endoprosthesis may be a balloon expandable endoprosthesis but more preferably is a self-expanding prosthesis. The constraining sheath is delicate, meaning that it is capable of retaining the endoprosthesis in a compressed state (i.e., at its small, compacted diameter) suitable for insertion into a body cavity, for a limited period of time. If left indefinitely around the endoprosthesis, such a delicate constraining sheath will yield to the diametrically outwardly directed force applied by a constrained self-expandable endoprosthesis. Accordingly, the delicate constraining sheath is enclosed within a packaging sheath of strength adequate to contain the endoprosthesis indefinitely, and is removed after the endoprosthesis is removed from its shipping package and prior to insertion of the endoprosthesis into a body cavity. The advantage of the use of such a delicate constraining sheath is its thin wall, which offers minimal interference when the constrained endoprosthesis is inserted into a body cavity such as the vasculature.

The constraining sheath may optionally be implantable, and as such, following deployment of the endoprosthesis, remains captive between the deployed endoprosthesis and the luminal surface of the body cavity at the site of implantation. Alternatively, the delicate constraining sheath may be attached to the delivery catheter and withdrawn with that catheter following deployment of the endoprosthesis. The constraining sheath is preferably made of ePTFE.

The constraining sheath and endoprosthesis are preferably mounted together as an assembly on an angioplasty balloon for delivery. Deployment of the endoprosthesis entails inflating the angioplasty balloon to a pressure sufficient to disrupt or break the constraining sheath in a prescribed fashion, thereby allowing a self-expanding endoprosthesis to spontaneously deploy.

II. PRELIMINARY REMARKS

A three-month extension of time is hereby requested. Please charge the appropriate fee to our Deposit Account No. 07-1729.

Restricted claims 43-48 are now canceled without prejudice.

III. CLAIM REJECTIONS

REJECTION OF CLAIMS 1-42 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER THORNTON et al. (US 6,015,431)

The Examiner states that the reference discloses an endoprosthesis assembly comprising a self-expanding stent, and a generally tubular delicate constraining sheath made of ePTFE with means for disruption (312) initiated by the application of a distending force. The Examiner further notes that Thornton et al. do not teach the use of a packaging sheath. It is concluded that it would be obvious to package the assembly of Thornton et al with a packaging sheath in order to keep it clean and sterile prior to use.

The Applicant would like to make the Examiner aware that the device described by Thornton et al. is manufactured and sold by the applicant under the tradename Excluder™ Bifurcated Endoprosthesis. This device is shipped within a sterile package; a portion of the length of the implantable device contained within the package is in turn contained within a tubular packaging sheath. The packaging sheath is used to ensure that the large diameter end of the bifurcated device will fit within the introducer tube used to introduce the device into the vasculature during surgery, even if the device is used on the final day of its stated shelf life. The Excluder™ Bifurcated Endoprosthesis "Instructions For Use" (dated 2002) makes reference to this packaging sheath (page 22, under the heading "Catheter Preparation," line 3). A photograph of the commercially available device is included in this response as "Attachment A." This packaging sheath was supplied commercially prior to the filing date of the present application.

Applicants respectfully disagree with the Examiner's conclusions as follows:

Thornton et al. describe a self-expanding endoprosthesis that is held in a constrained state (see Figures 4, 5, 12 and 13) by a "restraining sheath" (or "corset," see Thornton et al. beginning at col. 10, line 44) that is wrapped around the endoprosthesis and secured by a row of chain-stitches that release the stitched seam when tension is applied to an end of the strand that makes up the stitched seam. This restraining sheath is taught by Thornton et al. to be made of a material "...which is creep resistant and can withstand required loads without stretching over time" (see col. 11, line 65 to col. 12, line 11).

The present invention requires the use of a "delicate" constraining sheath that is not robust, as is the restraining sheath taught by Thornton et al. It is meant to be adequately strong to contain a compacted endoprosthesis for the time necessary to introduce it into the vasculature and to safely transport the device within the vasculature to the implant site. It is intended to have minimal profile so as to offer the least possible amount of interference during insertion into and through the vasculature. Accordingly, the constraining sheath of the present invention is thinner and more compact than a restraining sheath such as that taught by Thornton et al. For example, the seamed, stitched flange of

the restraining sheath of Thornton et al. (as clearly shown in the transverse cross section of Figure 5) is not within the scope of a minimal constraining sheath of the present invention. The "delicate" aspect of the constraining sheath of the present invention (and its need for a packaging sheath to limit the force to which it is exposed by the contained, compacted self-expanding endoprosthesis for all but short periods of time, as indicated by the dependent claims) is described in the present specification at page 6, line 29 to page 7, line 4; and page 21, line 16 to page 25, line 8. It is clear from this description that the delicate constraining sheath in combination with the other claimed elements of the endoprosthesis assembly is entirely contrary to the teachings of Thornton et al., and is consequently non-obvious in light of those teachings.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

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